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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,690	10/08/2003	Vincent Chau	MPI97-057P1RCP1CN1M	7707

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MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,690	CHAU, VINCENT	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7-9,14,23,25-27,30,31,33,34,36-38,43,44,46,47,49-51 and 56.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,4,5,7-9,14,23,25-27,30,31,33,34,36-38,43,44,46,47,49-51 and 56.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1, 2, 26, and 27, drawn to a NEDD8-activating protein beta subunit, classified in class 530, subclass 350.

II. Claim(s) 4, drawn to a NAE1-beta expression element selected from isolated or recombinant nucleic acid sequences encoding NEDD8-activating protein beta subunit, classified in class 536, subclass 23.1.

III. Claim(s) 5, drawn to a method for identifying NAE1BBMs comprising contacting purified NAE1-beta protein with molecules and determining the presence of molecules which bind specifically to NAE1-beta protein, classified in class 435, subclass 7.1.

IV. Claim(s) 7, drawn to a method for determining the presence or absence and/or quantity of NAE1-beta, NAE1 heterodimer, or NAE1 heterodimer/NEDD8 complex comprising NAE1-beta protein comprising providing a detectable NAE1BBM to a biological sample, allowing it to bind, and detecting presence or absence and/or quantity of a complex of detectable NAE1BBM and NAE1-heterodimer, or NAE1 heterodimer/NEDD8 complex, classified in class 435, subclass 7.71.

V. Claim(s) 8, drawn to a method for determining the presence or absence and/or quantity of NAE1-beta nucleic acid in a biological sample comprising providing to the biological sample a nucleic acid sequence which is specifically complementary to NAE1-beta nucleic acid, classified in class 435, subclass 6.

VI. Claim(s) 9, drawn to a method for identifying modulating ligands of NAE1-beta comprising providing NAE1BBMs to an assay system for NAE1-beta participation in the NEDD8-activation/conjugation pathway and determining whether such NAE1BBMs interfere with or enhance the ability of NAE1-beta to participate in the NEDD8-activation/conjugation pathway, classified in class 435, subclass 7.1.

VII. Claim(s) 14, drawn to a method of identifying NAEABMs comprising screening for NAE1ABMs by contacting purified NAE1-alpha and populations of molecules or mixed populations of molecules and determining the presence of molecules which bind specifically to NAE1-alpha, classified in class 435, subclass 7.1.

VIII. Claim(s) 23, drawn to a method for modulating the activation and/or conjugation of NEDD8 comprising providing a modulating ligand of NAE1-beta or NAE1-alpha or recombinant expression unit which expresses NAE1-beta or NAE1-alpha or an antagonist thereof to a biological system, classified in class 514, subclass 2.

IX. Claim(s) 25, drawn to a method for modulating APP function and/or beta peptide accumulation in a biological system comprising providing a modulating ligand of NAE1-beta or NAE1-alpha or recombinant expression unit which expresses NAE1-beta or NAE1-alpha or an antagonist thereof to a biological system, classified in class 514, subclass 2.

X. Claim(s) 30, 31, 56, drawn to purified NEDD8-conjugating enzyme 1, classified in class 530, subclass 350.

XI. Claim(s) 33, drawn to a NCE1 expression element selected from isolated or recombinant nucleic acid sequences encoding NEDD8-activating protein beta subunit, classified in class 536, subclass 23.1.

XII. Claim(s) 34, drawn to a method for identifying NCE1BMs comprising contacting purified NCE1 with molecules and determining the presence of molecules which bind specifically to NCE1, classified in class 435, subclass 7.1.

XIII. Claim(s) 36, drawn to a method for determining the presence or absence and/or quantity of NCE1 or NCE1/NEDD8 complex in a biological sample comprising providing a detectable NCE1BM to a biological sample, allowing it to bind, and detecting presence or absence and/or quantity of a complex of detectable NCE1BM and NCE1 or NCE1/NEDD8 complex, classified in class 435, subclass 7.1.

XIV. Claim(s) 37, drawn to a method for determining the presence or absence and/or quantity of NCE1 nucleic acid in a biological sample comprising providing to the

biological sample a nucleic acid sequence which is specifically complementary to NCE1 nucleic acid, classified in class 435, subclass 6.

XV. Claim(s) 38, drawn to drawn to a method for identifying modulating ligands of NCE1 comprising providing NCE1BMs to an assay system for NCE1 participation in the NEDD8-activation/conjugation pathway and determining whether such NCE1BMs interfere with or enhance the ability of NCE1 to participate in the NEDD8-activation/conjugation pathway, classified in class 435, subclass 7.1.

XVI. Claim(s) 43, 44, drawn to purified NEDD8-conjugating enzyme 2, classified in class 530, subclass 350.

XVII. Claim(s) 46, drawn to a NCE2 expression element selected from isolated or recombinant nucleic acid sequences encoding NCE2, classified in class 536, subclass 23.1.

XVIII. Claim(s) 47, drawn to a method for identifying NCE2BMs comprising contacting purified NCE2 with molecules and determining the presence of molecules which bind specifically to NCE2, classified in class 435, subclass 7.1.

XIX. Claim(s) 49, drawn to a method for determining the presence or absence and/or quantity of NCE2 or NCE2/NEDD8 complex in a biological sample comprising providing a detectable NCE2BM to a biological sample, allowing it to bind, and detecting presence or absence and/or quantity of a complex of detectable NCE2BM and NCE2 or NCE2/NEDD8 complex, classified in class 435, subclass 7.1.

XX. Claim(s) 50, drawn to a method for determining the presence or absence and/or quantity of NCE2 nucleic acid in a biological sample comprising providing to the biological sample a nucleic acid sequence which is specifically complementary to NCE2 nucleic acid, classified in class 435, subclass 6.

XXI. Claim(s) 51, drawn to a method for identifying modulating ligands of NCE2 comprising providing NCE2BMs to an assay system for NCE2 participation in the NEDD8-activation/conjugation pathway and determining whether such NCE2BMs interfere with or enhance the ability of NCE2 to participate in the NEDD8-

activation/conjugation pathway, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I, II, X, XI, XVI, and XVII are patentably distinct products because each of the products of Groups I, II, X, XI, XVI, and XVII are independent chemical entities that require different literature searches. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. The proteins of Groups I, X, and XVI are structurally distinct molecules with different amino acid sequences that require different literature searches.

Inventions of Groups III-IX, XII-XV, XVIII-XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups III-IX, XII-XV, XVIII-XXI are distinct both physically and functionally; require different process steps, reagents, and parameters; and have different purposes.

Inventions of Groups I, V, VII, VIII, IX, XII-XV, XVIII-XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups V, VII, VIII, IX, XII-XV, XVIII-XXI do not require the product of Group I.

Inventions of Groups II-IV, VI, VII, XII-XV, XVIII-XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups III, IV, VI, VII, XII-XV, XVIII-XXI do not require the product of Group II.

Inventions of Groups III-X, XIII, XVIII-XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups III-IX, XIII, XVIII-XXI do not require the product of Group X.

Inventions of Groups III-IX, XII, XIV, XV, XVIII-XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups III-IX, XII, XIV, XV, XVIII-XXI do not require the product of Group XI.

Inventions of Groups III-IX, XII-XVI, XX, and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP

§ 808.01). The processes of Groups III-IX, XII-XV, XX, and XXI do not require the product of Group XVI.

Inventions of Groups III-IX, XII-XVI, XVII-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups III-IX, XII-XVI, XVIII, XIX do not require the product of Group XVII.

Group I and Groups III, IV, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the protein in a process to make antibodies to the protein.

Group II and Groups V, VIII, IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the polynucleotide in a process to recombinant make a protein.

Group X and Groups XII, XIV, XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the protein in a process to make antibodies to the protein.

Group XI and Group XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the polynucleotide in a process to recombinant make a protein.

Group XVI and Groups XVIII and XIX are related as product and process of use. The

inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the protein in a process to make antibodies to the protein.

Group XVII and Groups XX and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the polynucleotide in a process to recombinant make a protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and classification, restriction for examination purposes as indicated is proper.

3. Group VIII and Group IX encompass patentably distinct compounds If Group VIII or Group IX is elected, applicants must elect only **one compound** for examination.

If Group VIII is elected, applicants must elect only one compound selected from:

1) a modulating ligand of NAE1- beta
2) a modulating ligand of NAE1- alpha
3) a recombinant expression unit which expressed NAE1-beta
4) a recombinant expression unit which expressed NAE1-alpha
5) an antagonist of NAE1- beta
6) an antagonist of NAE1- alpha

If Group IX is elected, applicants must elect only one compound selected from:

1) a modulating ligand of NAE1- beta
2) a modulating ligand of NAE1- alpha
3) a recombinant expression unit which expressed NAE1-beta
4) a recombinant expression unit which expressed NAE1-alpha
5) an antagonist of NAE1- beta
6) an antagonist of NAE1- alpha

Applicants are required under 35 U.S.C. 121 to elect a single compound as stated above, even though this requirement is traversed. Should applicant traverse on the ground that the compounds stated above are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600